SPECIFICATION

MODULAR STIMULATION LEAD NETWORK

Field Of The Invention

The invention relates to the implantation of stimulation leads within a patient, and in particular, the implantation of electrode leads within a patient's spine to treat disorders, such as chronic pain.

Background Of The Invention

It is known to treat chronic pain by electrically stimulating the spinal cord, spinal nerve roots, and other nerve bundles. Although not fully understood, the application of electrical energy to particular regions of the spinal cord induces parasthesia (i.e., a subjective sensation of numbness or tingling) in the afflicted body regions associated with the stimulated spinal regions. This parasthesia effectively masks the transmission of chronic pain sensations from the afflicted body regions to the brain. Since each body region is associated with a particular spinal nerve root, it is important that stimulation be applied at the proper longitudinal position along the spinal cord to provide successful pain management and avoid stimulation of unaffected regions of the body. Also, because nerve fibers extend between the brain and the nerve roots along the same side of the spine as the body regions they control, it is equally important that stimulation be applied at the proper lateral position of the spinal cord. For example, to treat unilateral pain (i.e., pain sensed only on one side of the body), electrical stimulation is applied to the corresponding side of the spinal cord. To treat bilateral pain (i.e., pain sensed on both sides of the body),

electrical stimulation is either applied directly to the midline of the spinal cord or applied to both lateral sides of the spinal cord.

In a typical procedure, one or more stimulation leads are introduced through the patient's back into the epidural space under fluoroscopy. The specific procedure used to implant the stimulation lead will ultimately depend on the type of stimulation lead used. Currently, there are two types of commercially available stimulation leads: a percutaneous lead and a surgical lead.

A percutaneous lead comprises a cylindrical body with ring electrodes, and can be introduced into contact with the affected spinal tissue through a Touhy-like needle, which passes through the skin, between the desired vertebrae, and into the spinal cavity above the dura layer. For unilateral pain, a percutaneous lead is placed on the corresponding lateral side of the spinal cord. For bilateral pain, a percutaneous lead is placed down the midline of the spinal cord, or two percutaneous leads are placed down the respective sides of the midline.

A surgical lead has a paddle on which multiple electrodes are arranged in independent columns, and is introduced into contact with the affected spinal tissue using a surgical procedure, and specifically, a laminectomy, which involves removal of the laminar vertebral tissue to allow both access to the dura layer and positioning of the lead.

After the stimulation lead(s) (whether percutaneous or surgical) are placed at the target area of the spinal cord, the lead(s) are anchored in place, and the proximal ends of the lead(s), or alternatively lead extensions, are passed through a tunnel leading to a subcutaneous pocket (typically made in the patient's abdominal area) where a neurostimulator is implanted. The lead(s) are connected to the neurostimulator, which is then operated to test the effect of stimulation and adjust the

parameters of the stimulation for optimal pain relief. During this procedure, the patient provides verbal feedback regarding the presence of paresthesia over the pain area. Based on this feedback, the lead position(s) may be adjusted and re-anchored if necessary. Any incisions are then closed to fully implant the system.

Various types of stimulation leads (both percutaneous and surgical), as well as stimulation sources and other components, for performing spinal cord stimulation are commercially available from Medtronic, Inc., located in Minneapolis, Minnesota, and Advanced Neuromodulation Systems, Inc., located in Plano, Texas.

The use of surgical leads provides several functional advantages over the use of percutaneous leads. For example, the paddle on a surgical leads has a greater footprint than that of a percutaneous lead. As a result, an implanted surgical lead is less apt to migrate from its optimum position than is an implanted percutaneous lead, thereby providing a more efficacious treatment and minimizing post operative procedures otherwise required to reposition the lead. As another example, the paddle of a surgical lead is insulated on one side. As a result, almost all of the stimulation energy is directed into the targeted neural tissue. The electrodes on the percutaneous leads, however, are entirely circumferentially exposed, so that much of the stimulation energy is directed away from the neural tissue. This ultimately translates into a lack of power efficiency, where percutaneous leads tend to exhaust a stimulator battery supply 25%-50% greater than that exhausted when surgical leads are used. As still another example, the multiple columns of electrodes on a surgical lead are well suited to address both unilateral and bilateral pain, where electrical energy may be administered using either column independently or administered using both columns.

Although surgical leads are functionally superior to percutaneous leads, there is one major drawback—surgical leads require painful surgery performed by a neurosurgeon, whereas percutaneous leads can be introduced into the epidural space minimally invasively by an anesthesiologist using local anesthesia.

There, thus, remains a need for a minimally invasive means of introducing stimulation leads within the spine of a patient, while preserving the functional advantages of a surgical lead.

Summary Of The Invention

Although the present inventions should not be so limited in their broadest aspects, they lend themselves well to medical applications, wherein access to a target site must be made through a limited opening, yet the resulting medical platform used to perform a medical procedure at such target site is larger than the access opening. The present inventions lend themselves particularly well to the percutaneous installation and subsequent operation of a stimulation lead assembly within the epidural space of a patient to treat ailments, such as chronic pain.

In accordance with a first aspect of the present inventions, a stimulation kit comprising first and second tissue stimulation leads is provided. The first stimulation lead comprises a first elongated body, a first stimulation element (e.g., an electrode), and a first coupling mechanism longitudinally extending along at least a portion of the first elongated body. The second stimulation lead comprises a second elongated body, a second stimulation element (e.g., an electrode), and a first complementary coupling mechanism configured to slidably engage the first coupling mechanism, e.g., in a rail and slot arrangement. The stimulation kit may optionally comprise a stimulation source configured to be coupled to the first and second stimulation leads.

Optionally, each of the stimulation leads comprises a plurality of stimulation elements in order to provide a more extensive stimulation coverage.

In one embodiment, the first and second elongated bodies are cylindrically-shaped, although other shapes are possible depending on the particular application. The size of the elongated bodies can be any size that is consistent with the stimulation procedure in which the stimulation leads will be employed. Although, for medical procedures, such as spinal cord stimulation, the greatest cross-sectional dimension of at least one of the elongated bodies is preferably 5 mm or less in order to minimize the size of the opening through which the stimulation leads will be introduced. The elongated bodies can have the same length, or alternatively, one elongated body can be shorter than the other, such that, e.g., the shorter elongated body can be entirely delivered within the patient's body without any portion extending from the access opening. In one embodiment, the stimulation elements of the respective stimulation leads face the same direction, e.g., to focus the stimulation energy in one direction.

The stimulation elements may be mounted directly on the elongated bodies, or alternatively, may be mounted to some other element of the stimulation leads. For example, the second stimulation lead may have a flap on which the respective stimulation element is disposed. In this case, the flap may extend along a portion of the complementary coupling mechanism, so that it can be secured by the coupling mechanism of the first stimulation lead when the portion of the complementary coupling mechanism slidably engages the coupling mechanism of the first stimulation lead and released by the coupling mechanism of the first stimulation lead when the portion of the complementary coupling mechanism slidably disengages the coupling mechanism of the first stimulation lead.

In one embodiment, the distal end of the second elongated body is configured to be in close contact with the first elongated body when engaging each other. Alternatively, the first elongated body is configured to deploy from the first elongated body by slidably disengaging at least a portion of the complementation coupling mechanism from the coupling mechanism of the first stimulation lead. In this case, the distal end of the second elongated body can be pre-curved to provide it with a predefined configuration. Optionally, the second elongated body may be configured to be actively changed from a first geometry to a second geometry after deployment from the first elongated body. For example, the kit may comprise a stylet configured to be introduced through the second elongated body to change the second elongated body from the first geometry to the second geometry. Or the secondary stimulation lead may comprise a pullwire configured to be pulled to change the second elongated body from the first geometry to the second geometry.

The kit may have more than two stimulation leads. For example, the first stimulation lead may comprise another coupling mechanism longitudinally extending along at least a portion of the respective elongated body, in which case, the kit may further comprise a third stimulation lead comprising an elongated body, a stimulation element mounted on the elongated body, and another complementary coupling mechanism configured to slidably engage the other coupling mechanism of the first stimulation lead.

In one preferred method of using the stimulation kit to treat a disorder (e.g., chronic pain) in a patient, the first stimulation lead is delivered into the epidural space of the patient's spine, and the second stimulation lead is delivered into the epidural space by sliding the complementary coupling mechanism along the coupling

mechanism of the first stimulation lead. Stimulation energy can then be conveyed from the stimulation elements into the neural tissue.

Preferably, the first and second stimulation leads are delivered through a percutaneous opening within the patient's skin, thereby minimizing patient discomfort and damage to otherwise healthy tissue. Although delivered in a minimally invasive manner, the larger footprint created by the coupled stimulation leads provides the assembly with more stability and greater coverage area. Thus, although not necessarily limited in its broadest aspects, the advantages of a surgical lead are retained by the present invention, without the disadvantages associated with invasive surgical procedures otherwise required to implant surgical leads.

In accordance with a second aspect of the present inventions, a method of treating a disorder (e.g., chronic pain) is provided. The method comprises delivering a first stimulation lead into the epidural space of the patient's spine, and delivering a second stimulation lead into the epidural space by slidably engaging the second stimulation lead along the first stimulation lead. A third stimulation lead can optionally be delivered into the epidural space by slidably engaging the third stimulation lead along the first stimulation lead. In one preferred method, the stimulation leads are delivered into the epidural space through a percutaneous opening. For example, the first stimulation lead can be introduced through a delivery device into the epidural space, and then the second stimulation lead can be delivered along the first stimulation lead.

In one preferred method, the stimulation leads are coupled to a stimulation source, in which case, the method may further comprise conveying stimulation energy (e.g., electrical energy) from the stimulation source to the stimulation leads to stimulate neural tissue within the patient's spine. The stimulation energy may be

focused into the neural tissue, as opposed to conveying the stimulation energy in all radial directions. In the preferred method, the stimulation leads are implanted within the patient's spine, e.g., to provide extended relief.

In accordance with a third aspect of the present inventions, a medical kit is provided. The medical kit is similar to the previously described stimulation kit, with the exception that the medical kit comprises first and second medical leads with respective operative elements that are not limited to stimulation elements, but rather can be any elements that are capable of performing a medical function within a targeted tissue region.

In accordance with a fourth aspect of the present inventions, a method of performing a medical procedure on a patient is provided. This method is similar to the previously described method, with the exception that it is not limited to stimulation of tissue within the epidural space of the patient.

In accordance with a fifth aspect of the present inventions, a stimulation kit is provided. The stimulation kit is similar to the previously described stimulation kit, with the exception that it comprises a guide and a stimulation lead. The guide is similar to the first stimulation lead of the previously described stimulation kit, with the exception that it need not have a stimulation element.

In accordance with a sixth aspect of the present inventions, a medical kit is provided. The medical kit is similar to the previously described medical kit, with the exception that it comprises a guide and a medical lead. The guide is similar to the first medical lead of the previously described medical kit, with the exception that it need not have an operative element.

Brief Description Of The Drawings

The drawings illustrate the design and utility of preferred embodiment(s) of the invention, in which similar elements are referred to by common reference numerals. In order to better appreciate the advantages and objects of the invention, reference should be made to the accompanying drawings that illustrate the preferred embodiment(s). The drawings, however, depict the embodiment(s) of the invention, and should not be taken as limiting its scope. With this caveat, the embodiment(s) of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Fig. 1 is a plan view of a modular stimulation lead kit arranged in accordance with a preferred embodiment of the present invention;

Fig. 2 is a cutaway top view of a stimulation lead assembly formed from the kit of **Fig. 1**;

Fig. 3 is a cutaway perspective view of a primary stimulation lead used in the kit of **Fig. 1**;

Fig. 4 is a cutaway perspective view of a secondary stimulation lead used in the kit of **Fig. 1**;

Fig. 5 is a cross-sectional view of the stimulation lead assembly of **Fig. 2**, taken along the **line 5-5**;

Fig. 6 is a cutaway view of an alternative stimulation lead assembly that can be formed from the kit of **Fig. 1**;

Fig. 7 is a cross-sectional view of the stimulation lead assembly of **Fig. 6**, taken along the **line 7-7**;

Figs. 8A-8D are various views illustrating the installation of the kit of **Fig. 1** into a patient's spine;

Fig. 9 is a plan view of another modular stimulation lead kit arranged in accordance with another preferred embodiment of the present invention;

Fig. 10 is a cutaway top view of a stimulation lead assembly formed from the kit of **Fig. 9**;

Fig. 11 is a cross-sectional view of the secondary stimulation lead of **Fig. 10**, taken along the **line 11-11**;

Figs. 12A-12B are various views illustrating the installation of the kit of **Fig. 9** into a patient's spine;

Fig. 13 is a partially cutaway top view of the distal end of an alternative primary stimulation lead that can be used in kit of **Fig. 1**;

Fig. 14a is a cutaway top view of an alternative stimulation lead assembly that can be formed from the kit of **Fig. 1** when the primary stimulation lead of **Fig. 13** is used, wherein the secondary stimulation leads are shown in a normally curved geometry that converges towards the primary stimulation lead;

Fig. 15a is a cross-sectional view of the stimulation lead assembly of **Fig. 14a**, taken along the **line 15a-15a**;

Fig. 14b is a cutaway top view of an alternative stimulation lead assembly that can be formed from the kit of **Fig. 1** when the primary stimulation lead of **Fig. 13** is used, wherein the secondary stimulation leads can be placed into a curved geometry that converges towards the primary stimulation lead when a stylet is introduced;

Fig. 15b is a cross-sectional view of the stimulation lead assembly of **Fig. 14b**, taken along the **line 15b-15b**;

Fig. 14c is a cutaway top view of another alternative stimulation lead assembly that can be formed from the kit of **Fig. 1** when the primary stimulation lead of **Fig. 13** is used, wherein the secondary stimulation leads can be placed into a

curved geometry that converges towards the primary stimulation lead when a pullwire is tensioned;

Fig. 15c is a cross-sectional view of the stimulation lead assembly of **Fig. 14c**, taken along the **line 15c-15c**;

Fig. 14d is a cutaway top view of still another alternative stimulation lead assembly that can be formed from the kit of **Fig. 1** when the primary stimulation lead of **Fig. 3** is used, wherein the secondary stimulation leads can be placed into a curved geometry that bows away from the primary stimulation lead;

Fig. 15d is a cross-sectional view of the stimulation lead assembly of **Fig. 14d**, taken along the **line 15d-15d**;

Fig. 15e is a cross-sectional view of the stimulation lead assembly of **Fig. 14d**, taken along the **line 15e-15e**;

Fig. 15f is a cross-sectional view of the stimulation lead assembly of **Fig. 14d**, taken along the **line 15f-15f**;

Fig. 16 is a cutaway top view of an alternative stimulation lead assembly;

Fig. 17 is a cross-sectional view of a portion of the stimulation lead assembly of **Fig. 16**, particularly showing an electrode flap of a secondary stimulation lead constrained by the primary stimulation lead; and

Fig. 18 is a cross-sectional view of a portion of the stimulation lead assembly of **Fig. 16**, particularly showing the electrode flap of the secondary stimulation lead released by the primary stimulation lead.

Detailed Description Of The Preferred Embodiments

Referring now to **Fig. 1**, a modular stimulation lead kit 100 arranged in accordance with one preferred embodiment of the present invention is shown. In its

simplest form, the stimulation kit 100 generally comprises a primary stimulation lead 102 and two secondary stimulation leads 104, which are configured to be percutaneously delivered and implanted into the epidural space of a patient's spine, an implantable electrical stimulation source 106 configured for delivering stimulation energy to the stimulation leads 102/104, and an optional extension lead 108 configured for connecting the stimulation leads 102/104 to the remotely implanted stimulation source 106. As will be described in further detail below, the secondary stimulation leads 104 can be attached to the primary stimulation lead 102 to form a modularized stimulation lead assembly 110, as illustrated in **Fig. 2**.

It should be noted that although the kit 100 illustrated in **Fig. 1** is described herein as being used in spinal cord stimulation (SCS) for the treatment of chronic pain, the kit 100, or a modification of the kit 100, can be used in an SCS procedure to treat other ailments, or can used in other applications other than SCS procedures, such as peripheral nervous system stimulation, sacral root stimulation, and brain tissue stimulation, including cortical and deep brain stimulation. In the latter case, the stimulation leads 102/104 can be delivered through a miniature cranial burr hole into the brain tissue.

The primary stimulation lead 102 comprises an elongated sheath body 112 having a proximal end 114 and a distal end 116. The sheath body 112 is composed of a suitably flexible material (such as polyurethane, silicone, etc.), which may either be resilient or non-resilient, and may be formed via an extrusion process or by any other suitable means. The distal end 116 of the sheath body 112 is soft and tapered to prevent injury to nerve roots that exit the spinal cord when delivered into the epidural space of the patient's spine. In the illustrated embodiment, the sheath body 112 is cylindrically-shaped and sized to fit through a Touhy-like needle (not shown).

In this case, the diameter of the sheath body 112 is preferably less than 5 mm to allow it to be percutaneously introduced through a needle. More preferably, the diameter of the sheath body 112 is within the range of 1 mm to 3 mm, so that the primary stimulation lead 102, along with the secondary stimulation leads 104 described below, can comfortably fit within the epidural space of the patient. The sheath body 112 may have other cross-sectional geometries, such as elliptical, rectangular, triangular, etc. If rectangular, the width of the primary stimulation lead 102 can be up to 5 mm, since the width of an epidural space is greater than its height. The sheath body 112 may have an optional lumen (not shown) for receiving a stylet (not shown) that axially stiffens the sheath body 112 to facilitate percutaneous introduction of the primary stimulation lead 102 within the epidural space of the patient's spine, as will be described in further detail below.

The primary stimulation lead 102 further comprises a plurality of terminals 118 (in this case, three) mounted on the proximal end 114 of the sheath body 112, and a plurality of stimulation elements, and in particular electrodes 120 (in this case, three), mounted on the distal end 116 of the sheath body 112. The terminals 118 are formed of ring-shaped elements composed of a suitable biocompatible metallic material, such as platinum, platinum/iridium, stainless steel, gold, or combinations or alloys of these materials, and can be mounted to the sheath body 112 in an interference fit arrangement.

In the illustrated embodiment, the electrodes 120 are formed on one circumferential side of the sheath body 112 (shown best in **Fig. 3**) in order to focus stimulation energy in one direction, thereby maximizing energy efficiency. The electrodes 120 can be formed onto the sheath body 112 using known deposition processes, such as sputtering, vapor deposition, ion beam deposition, electroplating

over a deposited seed layer, or a combination of these processes. Alternatively, the electrodes 120 can be formed onto the sheath body 112 as a thin sheet or foil of electrically conductive metal affixed to the wall of the sheath body 112. The electrodes 120 can be composed of the same electrically conductive and biocompatible material as the terminals 118, e.g., platinum, platinum/iridium, stainless steel, gold, or combinations or alloys of these materials.

The primary stimulation lead 102 further comprises a plurality of conductors 122 (shown in **Fig. 3**) extending through the sheath body 112 and connecting each electrode 120 with a respective terminal 118. The conductors 122 are composed of a suitably electrically conductive material that exhibits the desired mechanical properties of low resistance, corrosion resistance, flexibility, and strength.

Like the primary stimulation lead 102, each secondary stimulation lead 104 comprises an elongated sheath body 132 having a proximal end 134 and a distal end 136, a plurality of terminals 138 (in this case, four) mounted to the proximal end 134 of the sheath body 132, a plurality of electrodes 140 (in this case, four) mounted to the distal end 136 of the sheath body 132, and a plurality of conductors 142 (shown in **Fig. 4**) extending through the sheath body 132 and respectively connecting the electrodes 120 to the terminals 118. The sheath bodies 132 of the secondary stimulation leads 104 are similar to the sheath body 112 of the primary stimulation lead 102, with the exception that the distal ends 136 are tapered in only one direction. In this manner, the stimulation lead assembly 110, as illustrated in **Fig. 2**, forms a lower profile distal end to facilitate placement of the assembly 110 within the epidural space of the patient's spine. Like the sheath body 112 of the primary stimulation lead 102, the sheath bodies 132 of the secondary stimulation leads 104 may each have an optional lumen (not shown) for receiving a stylet (not

shown) to facilitate percutaneous introduction of the secondary stimulation lead 104 within the epidural space of the patient's spine, as will be described in further detail below.

The terminals 118 and electrodes 120 of the secondary stimulation leads 104 are similar to the terminals 118 and electrodes 120 of the primary stimulation lead 102, with the exception that there are four sets of terminals 118 and electrodes 120 instead of three. Notably, the electrodes 120 of the secondary stimulation leads 104 face the same direction as the electrodes 140 of the primary stimulation leads 102, so that the entire stimulation lead assembly 110 is capable of focusing electrical energy in a single direction, as shown in **Fig. 3**. Also, as illustrated in **Fig. 3**, the electrodes 120/140 are arranged on the respective sheath bodies 112/132, such that the electrodes 140 of the secondary stimulation leads 104 are offset from the electrodes 120 of the primary stimulation lead 102 in the longitudinal direction, thereby preventing accidental shorting between adjacent electrodes when the assembly 110 is formed.

Further details regarding the structure and composition of standard percutaneous stimulation leads are disclosed in U.S. Patent No. 6,216,045, which is expressly incorporated herein by reference.

The primary stimulation lead 102 and the respective secondary stimulation leads 104 are configured to slidably engage each other to form the lead assembly 110 illustrated in **Fig. 2**. In particular, referring to **Figs. 3-5**, the primary stimulation lead 102 comprises a pair of circumferentially opposed slots 150 extending along the length of the sheath body 112. The slots 150 can be formed in the sheath body 112 using any one of a variety of manners, but in the illustrated embodiment, the slots 150 are formed during the extrusion process. Alternatively, the slots 150 can be

formed by embedding, or otherwise mounting, discrete slotted members (not shown) along the sheath body 112. In contrast, each of the secondary stimulation leads 104 comprises a rail 152 extending along the sheath body 132. Like the slots 150, the rail 152 can be formed on the sheath body 132 using any one of a variety of manners, such as forming the rail 152 during the extrusion process. Alternatively, the rail 152 can be formed of a discrete member (not shown) that is bonded, or otherwise mounted, to the sheath body 132. In other embodiments, the primary stimulation lead 102 may have a pair of circumferentially opposed rails extending along its sheath body 112, while the secondary stimulation leads 104 may have slots 150 extending along their sheath bodies 132. In any event, the rails 152 and slots 150 are sized to snuggly engage each other in a sliding relationship, as best shown in **Fig. 5**.

Thus, it can be appreciated that the secondary stimulation leads 104 can be coupled to the primary stimulation lead 102 by sliding the rails 152 of the respective secondary stimulation leads 104 along the respective slots 150 of the primary stimulation lead 102, thereby forming the stimulation assembly 110 illustrated in **Fig. 2**. The opposing slots 150 of the primary stimulation lead 102 and the rails 152 of the secondary stimulation leads 104 are circumferentially offset ninety degrees from the centers of the respective electrodes 120. In this manner, all of the electrodes 120, which generally face in the same direction, as described above, are ensured to face in a direction perpendicular to the plane of the assembly 110, thereby maximizing transmission of the stimulation energy into the target neural tissue when the assembly 110 is fully implanted within the epidural space of the patient's spine.

Although a rail and slot arrangement has been disclosed as the preferred means of slidably engaging the primary and stimulation leads 102/104, other means

of slidably engaging the leads can be provided. For example, instead of slots, the primary stimulation lead can have loop structures (not shown) that extend along the opposing sides the respective sheath body. The secondary stimulation leads 104 can then be introduced through the respective sets of loop structures in order to couple the leads together.

In the illustrated embodiment, the slots 150 have distal rail stops (not shown), i.e., the distal ends of the slots 150 terminate prior to the distal tip of the sheath body 112 to prevent the distal ends 136 of the secondary stimulation leads 104 from sliding distal to the distal end 116 of the primary stimulation lead 102. Alternatively, the distal ends of the slots 150 may have chamfered openings 151, as illustrated in **Fig. 13**. In this manner, the distal ends of the secondary stimulation leads 104 will diverge from the distal end of the primary stimulation lead 102 when the leads 102/104 are slidably engaged with each other. That is, when the rail 152 of a secondary stimulation lead 104 is slid along the respective slot 150 of the primary stimulation lead 102, the distal end of the rail 152 will be diverted out of the chamfered opening 151 at the distal end of the slot 150, thereby expanding the footprint of the resulting assembly 110, as illustrated in **Fig. 14a**. The secondary stimulation lead 104 may have a proximal rail stop (not shown) to prevent further sliding of the respective secondary stimulation lead 104 when fully deployed.

The distal ends of the secondary stimulation leads 104 can be pre-curved inward towards the primary stimulation lead 102, as illustrated in **Fig. 14a**, so that the distal ends of the secondary stimulation leads 104, when deployed from the primary stimulation lead 102, extend in a parallel direction with the distal end of the primary stimulation lead 102. The distal ends of the secondary stimulation leads 104 can be pre-curved in any one of a variety of manners. For example, as illustrated in

Fig. 15a, a pre-curved resilient member 153 composed of a suitable material, such as nitinol, can be formed within the sheath body 132. Preferably, the cross-section of the resilient member 153 resembles of flat plate, so that the sheath body 132 consistently bends in a pre-defined plane, i.e., within the plane of the assembly 110.

Alternatively, as illustrated in **Fig. 14b**, the distal ends of the secondary stimulation leads 104 are not pre-curved, but rather normally exhibit a straight geometry after exiting slot 150 of the primary stimulation lead 102 (shown in phantom in **Fig. 14b**), such that the distal ends of the secondary stimulation leads 104 diverge from the primary stimulation lead 102. Alternatively, the distal ends of the secondary stimulation leads 104 may not be resilient. In either case, the secondary stimulation lead 104 comprises a lumen 155 through which a curved stylet 157 is introduced, as illustrated in **Fig. 15b**. The distal end of the stylet 157 is curved, such that, when introduced through the lumen 155, the distal end of the respective stimulation lead 104 assumes a geometry that curves inward towards the primary stimulation lead 102, as illustrated in **Fig. 14b**. Differently curved stylets 157 can be used in order to provide the distal end of the secondary stimulation lead 104 with the desired curved geometry. Alternatively, rather than providing a curved stylet 157 and a normally straight secondary stimulation lead 104, the distal end of the secondary stimulation lead 104 can be pre-curved much like the stimulation lead 104 illustrated in **Fig. 14a**. In this case, the distal end of the stylet 157 can be straight, so that its introduction through the lumen 157 straightens the pre-curved distal end of the secondary stimulation lead 104, as shown in phantom in **Fig. 14b**.

As another alternative, a steering mechanism can be used to control the shape of the secondary stimulation lead 104. In particular, as illustrated in **Fig. 14c**, the distal ends of the secondary stimulation leads 104 normally exhibit a straight

geometry, in which case, the resilient member 153 is likewise formed into a straight geometry. As illustrated in **Fig. 15c**, the secondary stimulation lead 104 comprises a pullwire lumen 159 and an associated pullwire 161 mounted to the inside surface of the distal end of the resilient member 153. When the pullwire 161 is relaxed, the distal end of the secondary stimulation lead 104 assumes the straight geometry. In this case, the distal ends of the secondary stimulation leads 104 diverge from the primary stimulation lead 102, as illustrated in **Fig. 14c**. In contrast, when the pullwire 161 is pulled, the distal end of the secondary stimulation lead 104 assumes a geometry (shown in phantom) that curves inward towards the primary stimulation lead 102. Notably, the proximal-most portion of the distal ends of the secondary stimulation leads 104 does not contain the resilient member 153, so that the respective stimulation lead 104 bends at this portion when the pullwire 161 is pulled. Rather than providing a normally straight secondary stimulation lead 104, the distal end of the secondary stimulation lead 104 can be pre-curved much like the stimulation lead 104 illustrated in **Fig. 14a**. In this case, the pullwire 161 can be mounted to the outside surface of the distal end of the resilient member 153, such that relaxation of the pullwire 161 causes the distal end of the secondary stimulation lead 104 to assume a curved geometry that converges towards the primary stimulation lead 102, whereas the application of tension on the pullwire 161 causes the distal end of the secondary stimulation lead 104 to assume a lesser curved or straight geometry that diverges from the primary stimulation lead 102.

As still another alternative, a portion of the secondary stimulation lead 104 may not have a rail, so that it bows outward after the primary stimulation lead 102 and secondary stimulation lead 104 are fully engaged, as illustrated in **Fig. 14d**. As best seen in **Figs. 15d-f** , the rail 152 extends along the distal-most and proximal-

most portions of the distal end of the second stimulation lead 104, but does not extend along a medial-portion of the distal end of the second stimulation lead 104. As a result, after the distal end of the respective rail 152 (i.e., the rail 152 located on the distal-most portion of the second stimulation lead 104) abuts the distal rail stop (not shown) in the corresponding slot 150, further distal movement of the secondary stimulation lead 104 relative to the primary stimulation lead 102 causes the medial-portion, which is not engaged with the slot 150 of the primary stimulation lead 102, to bow outward from a straight geometry (shown in phantom). In contrast, proximal movement of the secondary stimulation lead 104 relative to the primary stimulation lead 102 causes the medial-portion to return from the bowed geometry back to its straight geometry.

It should be noted that although the assemblies 110 illustrated in **Figs. 2** and **14a-d** are formed of three stimulation leads, less or more than three stimulation leads can be used. For example, if an assembly formed only of two stimulation leads is desired, only one slot 150 on the primary stimulation lead 102 is required. In this case, the primary stimulation lead 102 may only have one slot 150 formed along one side of the respective body 112, or alternatively, if the primary stimulation lead 102 comprises two opposing slots 150, only one will be used to couple the lone secondary stimulation lead 104 thereto. On the other hand, if an assembly formed of more than three stimulation leads is desired, the secondary stimulation leads 104 may have a pair of circumferentially opposed rails 152. For example, if there are five stimulation leads, two secondary stimulation leads 103 (which are similar to the secondary stimulation leads 104, but with a pair of circumferentially opposing rails 152) can be coupled to the primary stimulation lead 102 by sliding the rails 152 of the respective secondary stimulation leads 104 along the respective slots 150 of the

primary stimulation lead 102, thereby forming a partial assembly similar to that illustrated in **Fig. 3**. Then, two additional secondary stimulation leads 105 (which are similar to secondary stimulation leads 105, but have a pair of circumferentially opposed slots 150) can be coupled to the secondary stimulation leads 105 by sliding the slots 150 of the additional secondary stimulation leads 102 along the respective rails 152, thereby forming a full assembly 160, as illustrated in **Figs. 6** and **7**.

Referring back to **Fig. 1**, the implantable stimulation source 106 is designed to deliver electrical pulses to the stimulation leads 102/104 in accordance with programmed parameters. In the preferred embodiment, the stimulation source 106 is programmed to output electrical pulses having amplitudes varying from 0.1 to 20 volts, pulse widths varying from 0.02 to 1.5 milliseconds, and repetition rates varying from 2 to 2500 Hertz. In the illustrated embodiment, the stimulation source 106 takes the form of a totally self-contained generator, which once implanted, may be activated and controlled by an outside telemetry source, e.g., a small magnet. In this case, the pulse generator has an internal power source that limits the life of the pulse generator to a few years, and after the power source is expended, the pulse generator must be replaced. Generally, these types of stimulation sources 106 may be implanted within the chest or abdominal region beneath the skin of the patient.

Alternatively, the implantable stimulation source 106 may take the form of a passive receiver that receives radio frequency (RF) signals from an external transmitter worn by the patient. In this scenario, the life of the stimulation source 106 is virtually unlimited, since the stimulation signals originate from the external transmitter. Like the self-contained generators, the receivers of these types of stimulation sources 106 can be implanted within the chest or abdominal region beneath the skin of the patient. The receivers may also be suitable for implantation

behind the ear of the patient, in which case, the external transmitter may be worn on the ear of the patient in a manner similar to that of a hearing aid. Stimulation sources, such as those just described, are commercially available from Advanced Neuromodulation Systems, Inc., located in Plano, Texas, and Medtronic, Inc., located in Minneapolis, Minnesota.

The optional extension lead 108 comprises an elongated sheath body 144 having a proximal end 146 and a distal end 148, much like the sheath bodies 112/132 of the stimulation leads 102/104, a distal adapter 154 coupled to the distal end 148 of the sheath body 144, a connector 156 coupled to the proximal end 146 of the sheath body 144, and a plurality of electrical conductors (not shown) extending through the sheath body 144. The length of the extension lead 108 is sufficient to extend from the spine of the patient, where the proximal ends of the implanted stimulation leads 102/104 protrude from to the implantation site of the stimulation source 106—typically somewhere in the chest or abdominal region. The distal adapter 154 is configured to receive the proximal ends of the stimulation leads 102/104, and the proximal connector 156 is configured to couple to the stimulation source 106.

Having described the stimulation lead kit 100, its installation and use in treating chronic pain will now be described with reference to **Figs. 8A-8D**. After the patient has been prepared (which may involve testing the efficacy of spinal cord stimulation on the patient, and, once determining that the patient can be effectively treated with spinal cord stimulation, identifying and marking the appropriate vertebral intervals on the patient's skin and applying a local anesthetic to this region), a needle 10, such as, e.g., a Touhy needle, is inserted through the patient's skin 12 between the desired vertebrae 14, and into the epidural space 16 within the spine at a

position inferior to target stimulation site 18 (**Fig. 8A**). In the illustrated method, the Touhy needle 10 will serve as the primary delivery mechanism for the primary stimulation lead 102. Alternatively, if an optional introducer (not shown) is used, a guide wire (not shown) is introduced through the needle 10 and advanced to or near the target stimulation site 18. The needle 10 is removed, the introducer is then introduced over the guide wire and advanced to the target stimulation site 18, and the guide wire is then withdrawn. In this case, the introducer will serve as the primary delivery mechanism for the primary stimulation lead 102.

After the deliver mechanism is in place, the primary stimulation lead 102 is then inserted through the needle or the introducer (whichever is in place), and positioned in the epidural space at the target stimulation site 18, with the electrodes 120 facing the dural layer 20 surrounding the spinal cord 22 (**Fig. 8B**). If the primary stimulation lead 102 has a stylet lumen, a stylet can be used to provide additional axial stiffness and to facilitate control. Next, the needle 10 or introducer is removed, and one of the secondary stimulation leads 104 is delivered through the percutaneous opening 24 left by the removal of the needle 10, and into the epidural space 16 by slidably engaging the secondary stimulation lead 104 along the primary stimulation lead 102 (**Fig. 8C**). In particular, the rail 152 of the secondary stimulation lead 104 is inserted into the corresponding slot 150 of the primary stimulation lead 102, and the secondary stimulation lead 104 is pushed until the distal end of the rail 152 abuts the distal end of the slot 150, thereby signifying that the secondary stimulation lead 104 is fully engaged with the primary stimulation lead 102 (with the electrodes 120/140 of the stimulation leads 102/104 adjacent, but offset from, each other) and is in its proper location within the epidural space 16 of the patient. The other secondary stimulation lead 104 is then delivered into the epidural space by

slidably engaging it along the primary stimulation lead 102 in the same manner, thereby completing the stimulation lead assembly 110 (**Fig. 8D**). If the secondary stimulation leads 104 have stylet lumens, a stylet can be used to provide additional axial stiffness and to facilitate control. Once the assembly 110 is completed, the electrodes 120/140 will span the midline of the spinal cord 22, much like the electrodes of a standard surgical lead do.

Next, the proximal ends of the stimulation leads 102/104 are connected to a tester (not shown), which is then operated in a standard manner to confirm proper location of the stimulation lead assembly 110 and to adjust the stimulation parameters for optimal pain relief. Once this optimization process has been completed, the tester is disconnected from the stimulation leads 102/104, which are then anchored in place using standard lead anchors (not shown). Next, the stimulation lead assembly 110 is coupled to the stimulation source 106 and implantation is completed (not shown). In particular, a subcutaneous pocket is created in the patient's abdominal area for implantation of the stimulation source 106, and a tunnel is subcutaneously formed between the spine region and the subcutaneous pocket. The optional lead extension 108 is passed through the tunnel, after which the adapter 154 of the extension 108 is connected to the proximal ends of the stimulation leads 102/104 and the connector 156 of the lead extension 108 is connected to the stimulation source 106. The stimulation source 106 is programmed and tested, and then placed within the subcutaneous pocket, after which all incisions are closed to effect implantation of the stimulation lead assembly 110 and stimulation source 106. The stimulation source 106 can then be operated to convey stimulation energy from the stimulation source 106 to the electrodes 120/140 of the stimulation lead assembly 110, where it is, in turn, conveyed into the neural tissue for pain relief.

If necessary or desired, e.g., if the electrodes 120/140 malfunction or stimulation otherwise ceases to provide therapeutic benefit, the stimulation lead assembly 110 can be subsequently retrieved from the patient's spine by removing the assembly 110 at the same time or by removing the assembly one stimulation lead 102/104 at a time by slidably disengaging the stimulation leads 102/104. In the case of the assembly 110 illustrated in **Fig. 14**, the rail and slot arrangement will pull the deployed distal end of the secondary stimulation leads 104 along side of the primary stimulation lead 102 when retrieved.

It can be appreciated that the relatively large footprint made by the stimulation lead assembly 110, much like a prior art surgical lead, provides a more stable platform for the electrodes 120/140. Also, like a prior art surgical lead, the electrodes 120/140 face in a single direction, thereby focusing the stimulation energy into the affected neural tissue where it is needed. Unlike a surgical lead, however, the stimulation lead assembly 110 can be percutaneously delivered into the patient's spine in a minimally invasive and relatively pain-free manner, without requiring extensive patient recovery.

Referring now to **Fig. 9**, a modular stimulation lead kit 200 arranged in accordance with another preferred embodiment of the present invention is shown. The kit 200 is similar to the previously described kit 100, with the exception that the kit 200 comprises secondary stimulation leads 204 that minimize the profile of the resulting assembly (shown in **Fig. 10**), as it exits the spine of the patient. In particular, each secondary stimulation lead 204 comprises a shortened sheath body 232, electrodes 240 mounted to the sheath body 232, electrical conductors 242 extending from the sheath body 232, and a connector 244 that receives the proximal ends of the electrical conductors 242. The connector 244 comprises a plurality of

terminals 238 that are similar to the previously described lead terminals 138. The sheath body 232 is composed of the same material and has the same general shape as the sheath body 132 of the previously described secondary stimulation lead 104. The sheath body 232, as illustrated in **Fig. 9**, however, is much shorter, so that it can be entirely received within the epidural space of the patient, i.e., the sheath body 232 will not extend out of the patient's back when fully deployed within the epidural space. The electrical conductors 242, because they are exposed, are preferably composed of an electrically insulative material.

The kit 200 further comprises a pusher 214 that can be used to facilitate introduction of the respective secondary stimulation lead 204 along the primary stimulation lead 102 once the entire sheath body 232 of the secondary stimulation lead 204 is within the patient's back. The pusher 214 comprises a cylindrical rod 216 having a distal tip 218 and a proximal end 220, and a handle 222 mounted on the proximal end 220 of the rod 216. The distal tip 218 of the rod 216 is adapted to be received within an opening 224 (shown in **Fig. 11**) at the proximal end of the sheath body 232, thereby facilitating stable engagement between the pusher 214 and respective secondary stimulation lead 204.

The kit 200 can be installed and used in the same manner as the previously described kit 100 in treating chronic pain. In particular, the patient is prepared and the primary stimulation lead 102 is delivered into the epidural space 16 of the patient's spine, so that the electrodes 120 are placed adjacent the target stimulation site 18 in the same manner described above with respect to **Fig. 8A** and **8B**. One of the secondary stimulation leads 204 is then delivered into the epidural space 16 in the same manner as the secondary stimulation lead 104 described above was delivered, with the exception that the pusher 214 is used to advance the secondary

stimulation lead 204 along the primary stimulation lead 102 until fully deployed within the epidural space 16 (**Fig. 12A**). The remaining stimulation lead 204 is delivered into the epidural space 16 in the same manner to complete the stimulation lead assembly 210 (**Fig. 12B**).

Notably, because the percutaneous opening 24 need only support, at most, two sheath bodies at one time, it can be made smaller, or alternatively, additional stimulation leads with shortened sheath bodies can be introduced within the epidural space 16 without increasing the size of the percutaneous opening. After the stimulation lead assembly 210 has been formed within the epidural space, it is tested and optimized. The extension lead 108 is then connected between the stimulation leads 102/204 and the stimulation source 106, and the incisions are closed to fully implant the system, as previously described above.

Referring now to **Fig. 16**, an alternative embodiment of a secondary stimulation lead 304 engaged with one side of the primary stimulation 102 is illustrated. Although not shown, another secondary stimulation lead 304 can be engaged with the opposite side of the primary stimulation lead 102. The secondary stimulation lead 304 is similar to the previously described secondary stimulation lead 104, with the exception that the secondary stimulation lead 304 comprises a flap 303 on which the electrodes 140 are mounted. The secondary stimulation lead 304 can, alternatively, have a shortened sheath body much like the secondary stimulation lead 204 illustrated in **Fig. 9**. The flap 303 is designed to be constrained by the primary stimulation lead 102 to facilitate percutaneous delivery of the secondary stimulation lead 102, and released by the primary stimulation lead 102 to deploy the electrodes 140 into contact with the neural tissue.

In particular, the edge of the flap 303 comprises a coupling mechanism 305 that is designed to fit snugly within the respective slot 150 of the primary stimulation lead 102, along with the rail 152 of the secondary stimulation lead 102, when the secondary stimulation lead 304 is slidably engaged with the primary stimulation lead 102, as illustrated in **Fig. 17**. As the rail 152 of the secondary stimulation lead 102 exits the slot 150 of the primary stimulation lead 102, however, the coupling mechanism 305 of the flap 303 will release from the slot 150, thereby allowing the flap 303 to deploy, placing the electrodes 140 into contact with the underlying tissue, as illustrated in **Fig. 18**. It should be noted, that, when the secondary stimulation lead 304 is used in the kit 100 or kit 200, the slots 150 in the primary stimulation lead 102 will not terminate as hereinbefore described, but will rather open up at the distal tip of the primary stimulation lead 102, so that the flap 303 can exit the respective slot 150 and be released by the primary stimulation lead 102.

Installation and use of the secondary stimulation lead 304 in forming the stimulation lead assembly 110 illustrated in **Fig. 2**, or alternatively the stimulation lead assembly 210 illustrated in **Fig. 10**, is similar that previously described above.

Although in all of the previous embodiments, the primary stimulation lead 102 was used to provide a means of guiding the secondary stimulation leads 104 into the percutaneous opening within the patient and adjacent the target tissue region, as well as to provide a means of stimulating the tissue region, a guide member similar to the primary stimulation lead 102, but lacking stimulation capability, can be alternatively used to similarly guide the secondary stimulation leads 104 through the percutaneous opening to the target tissue region. In this case, only the secondary stimulation leads 104 will be used to stimulate tissue.

Although particular embodiments of the present invention have been shown and described, it should be understood that the above discussion is not intended to limit the present invention to these embodiments. It will be obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the present invention. Thus, the present invention is intended to cover alternatives, modifications, and equivalents that may fall within the spirit and scope of the present invention as defined by the claims.